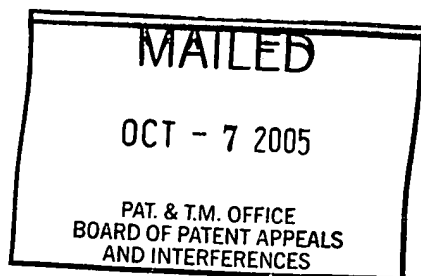




## UNITED STATES PATENT AND TRADEMARK OFFICE

DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BOARD OF PATENT APPEALS AND INTERFERENCES  
BOX INTERFERENCE, WASHINGTON, D.C. 20231

Filed by: Fred E. McKelvey  
Telephone: (571) 272-9797  
Facsimile: (571) 273-0042



Applicants: Aronhime et al.  
Application No.: 09/997,126  
Filed: 11/29/01  
For: Novel crystal forms of  
atorvastatin hemi-calcium and processes  
for their preparation as well as novel  
processes for preparing other forms

The above-identified application or patent has been forwarded to the Board of Patent Appeals and Interferences because it is adjudged to interfere with another application or patent. An interference has been declared. The interference is designated as No. 105,384.

Notice is hereby given the parties of the requirement of the law for filing in the Patent and Trademark Office a copy of any agreement "in connection with or in contemplation of the termination of the interference." 35 U.S.C. § 135(c).

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Fred E. McKelvey  
Senior Administrative Patent Judge

## INTERFERENCE DIGEST

Interference No. 105,384

Paper No.

Name: Judith Aronhime et al.

Serial No.: 09/997,126

Patent No.

Title: Novel crystal forms of atorvastatin hemi-calcium and processes for their preparation as well as novel processes for preparing other forms

Filed: 11/29/01

Interference with Byrn et al.

## DECISION ON MOTIONS

Administrative Patent Judge, \_\_\_\_\_ Dated, \_\_\_\_\_

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## FINAL DECISION

Board of Patent Appeals and Interferences, \_\_\_\_\_ Dated, \_\_\_\_\_

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Court, \_\_\_\_\_ Dated, \_\_\_\_\_

## REMARKS

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Mail Stop Interference  
P.O. Box 1450  
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Tel: 571-272-9797  
Fax: 571-273-0042

Filed 7 October 2005

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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STEPHEN ROBERT BYRN, DAVID ANDREW COATES,  
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,  
ZHENG JANE LI, HENRY GRANT MORRISON II,  
AERI PARK and PETINKA IVANOVA VLAHOVA,

Junior Party  
(Patent 6,605,729 B1),

v.

JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM,  
REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party  
(Application 09/997,126).

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Patent Interference No. 105,384-McK  
Technology Center 1600

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**DECLARATION - Bd.R. 203(d)**

**Part A. Declaration of interference**

An interference is declared (35 U.S.C. § 135(a)) between the above-identified parties. Details of the application, patent, count and claims designated as corresponding or as not corresponding to the count appear in Parts E and F of this DECLARATION.

**Part B. Judge managing the interference**

Administrative Patent Judge McKelvey has been designated to manage the interference. 37 CFR § 41.104(a) [Bd. R. 104(a)].

**MAILED**

**OCT - 7 2005**

PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES

**Part C. Standing order**

A Trial Section STANDING ORDER (Paper 2) accompanies this DECLARATION. The STANDING ORDER applies to this interference.

**Part D. Initial conference call**

A telephone conference call to discuss the interference is set for 1:30 p.m. (1330 hours Eastern Time) on Monday, 21 November 2005 (the Board will initiate the call).

No later than two business days (i.e., Thursday, 17 November 2005) prior to the conference call, each party shall file and serve by facsimile (STANDING ORDER ¶ 4.5) a list of the motions (Bd. R. 120; Bd. R. 204; STANDING ORDER ¶ 26) the party intends to file.

A sample schedule for taking action during the motion phase appears as Form 2 in the STANDING ORDER. Counsel are encouraged to discuss the schedule prior to the conference call and to agree on dates for taking action. A typical motion period lasts approximately eight (8) months. Counsel should be prepared to justify any request for a shorter or longer period.

**Part E. Identification and order of the parties**

Junior Party

Named inventors: Stephen Robert Byrn  
West Lafayette, IN

David Andrew Coates  
West Lafayette, IN

Karen Sue Gushurst  
Lafayette, IN

Joseph Francis Krzyzaniak,  
Pawcatuck, CT

Zheng Jane Li  
Quaker Hill, CT

Henry Grant Morrison II  
Lafayette, IN

Aeri Park  
West Lafayette, IN

Petinka Ivanova Vlahova  
Lafayette, IN

Patent: U.S. Patent 6,605,729 B1  
issued 12 August 2003  
based on application 10/184,669  
filed 28 June 2002

Title: Crystalline forms of [R, -(R\*, R\*)]-  
2-(4-fluorophenyl)- $\beta$ ,  $\delta$ -dihydroxy-5-  
(1-methylethyl)-3-phenyl-4-  
[(phenylamino)carbonyl]-1H-pyrrole-  
1-heptanoic acid calcium salt (2:1)

Assignee: Warner-Lambert Company

Accorded Benefit: Provisional application 60/302,049  
filed 29 June 2001

Senior Party

Named Inventors: Judith Aronhime, Israel  
Ramy Lidor-Hadas, Israel  
Valerie Niddam, Israel  
Revital Lifshitz, Israel  
Guy Sambursky, Israel

Application: Application 09/997,126,  
filed 29 November 2001

Title: Novel crystal forms of atorvastatin  
hemi-calcium and processes for  
their preparation as well as novel  
processes for preparing other forms

Assignee: Teva Pharmaceutical Industries Ltd

Accorded Benefit: Provisional application 60/267,897,  
filed 09 February 2001<sup>1</sup>

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<sup>1</sup> Aronhime also claims priority based on the following provisional applications:

- (1) provisional application 60/250,072, filed 30 November 2000,
- (2) provisional application 60/281,872, filed 05 April 2001,
- (3) provisional application 60/312,144, filed 13 August 2001 and
- (4) provisional application 60/326,529, filed 01 October 2001.

If Aronhime thinks that it is entitled to benefit for the purpose of priority of one or more of these provisional applications, it may list a motion for benefit when it submits its motions list. 37 CFR § 41.204(b) (2005); 69 Fed. Reg. 50019 (Aug. 12, 2004). The files of these provisional applications are being maintained with the records of the interference; copies may be ordered directly with the board.

The senior party is assigned exhibit numbers 1001-1999.  
Bd. R. 154(c)(1).

The junior party is assigned exhibit numbers 2001-2999.  
Bd. R. 154(c)(1).

The senior party is responsible for initiating settlement discussions. STANDING ORDER ¶ 18.

Part F. Count and claims of the parties

Count 1

A crystalline Form VIII atorvastatin hemi-calcium and solvates thereof characterized by a powder X-ray diffraction pattern generated using  $\text{CuK}_\alpha$  radiation with peaks at

4.8  
5.2  
8.0  
9.2  
9.6  
19.0  
20.0  
24.0 and  
29.0

$\pm 0.2$  degrees two-theta

or

a crystalline Form X atorvastatin or a hydrate thereof having an X-ray powder diffraction containing the following  $2\theta$  values measured using  $\text{CuK}_\alpha$  radiation:

4.7  
5.2  
5.8  
6.9  
7.9  
9.2  
9.5  
10.3 (broad)  
11.8  
16.1  
16.9  
19.1  
19.8  
21.4  
22.3 (broad)  
23.7 (broad)  
24.4 and  
28.7.



The claims of the parties are:

Byrn: 1-15

Aronhime: 147-166

The claims of the parties which correspond to Count 1 are:

Byrn: 6

Aronhime: 147-166

The claims of the parties which do not correspond to Count 1, and therefore are not involved in the interference, are:

Byrn: 1-5 and 7-15

Aronhime: None

**Part G. Heading to be used on papers**

The heading in STANDING ORDER Form 1 must be used on all papers filed in this interference. See STANDING ORDER ¶ 7.2.1. The administrative patent judge and parties must be indicated as follows:

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

STEPHEN ROBERT BYRN, DAVID ANDREW COATES,  
KAREN SUE GUSHURST, JOSEPH FRANCIS KRZYZANIAK,  
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AERI PARK and PETINKA IVANOVA VLAHOVA,

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JUDITH ARONHIME, RAMY LIDOR-HADAS, VALERIE NIDDAM,  
REVITAL LIFSHITZ and GUY SAMBURSKY,

Senior Party  
(Application 09/997,126).

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Patent Interference No. 105,384--McK  
Technology Center 1600

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**Part H. Order form for requesting file copies**

When requesting copies of files, use of STANDING ORDER Form 4 will greatly expedite processing of the request. Please attach a copy of Part E of this DECLARATION with a hand-drawn circle around the patents and applications for which a copy of a file wrapper is requested.

**Part I. Required paragraph for affidavits and declarations**

The Board has recently experienced a rash of cases in which a witness has belatedly advanced reasons why he or she would be unable to appear for cross examination at a reasonable time and place in the United States. Consequently, the Board is requiring the following paragraph to be included on the signature page of all affidavits (including declarations) filed in this case to prevent surprise and hardship to the party relying on the testimony of the witness:

In signing this affidavit/declaration, I recognize that the affidavit/declaration will be filed as evidence in a contested case before the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

/Fred E. McKelvey/<sup>2</sup>

FRED E. MCKELVEY,  
Senior Administrative Patent Judge

07 October 2005  
Alexandria, VA

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<sup>2</sup> As part of Board efforts under the Government Paperwork Elimination Act, signatures on papers originating from the Board are being phased out in favor of a completely electronic record. Consequently, in this case papers originating at the Board will not have signatures. The signature requirements for the parties have not changed. See, e.g., 37 CFR § 10.18.

Enc (there is no Form PTO-850):

STANDING ORDER (Paper 2)

DVD program

e-filing program

U.S. Patent 6,605,729 B1

Claims 147-166 of application 09/997,126

Specification, abstract and drawings (as filed)  
of application 09/997,126

Oath of application 09/997,126

Specification, oath, abstract and drawings (as filed)  
of application 10/860,084

Claims of application 10/860,084

Request under 37 CFR § 1.607 for declaration of an  
interference filed 28 July 2004 in application  
09/997,126

Bibliographic data for applications 10/860,084 and  
09/997,126 and 10/184,669

Revised January 2005

cc (via overnight delivery):

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